

**CREDENTIALING PROCESS AND SCOPE OF PRACTICE FOR INDIVIDUALS INVOLVED  
IN RESEARCH**

**1. PURPOSE:** To establish policy & procedure for credentialing or otherwise validating the qualifications of individuals who conduct or participate in Albany VAMC research, heretofore referred to as ‘research staff’ and to detail functions and responsibilities, through the completion of a Scope of Practice or detailed research protocols, of all personnel engaged in research, as well as the roles of Stratton VAMC offices, including Research & Development, Human Resources, and Quality Management.

**2. BACKGROUND:** The Department of Veterans Affairs (DVA) is guided by ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies, it is imperative that all personnel involved in research have and maintain the appropriate expertise through education, training, and experience.

**3. DEFINITIONS:**

**a. Credentialing:** Credentialing is the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials that include formal education, licensure, relevant training experience, and current competence.

**b. Scope of Practice:** The Scope of Practice outlines the duties which the Principal Investigator (PI) authorizes the research employee to perform during the conduct of a research project. The Scope of Practice is used for those who are engaged in any type of research.

**4. POLICY:** It is VHA policy that all individuals who participate in VA research must have some form of VA appointment. And, regardless of appointment mechanism [Title 38, Title 5, or Without Compensation (WOC) and those appointed by the Intergovernmental Personnel Act Mobility Program (IPA)], they must possess adequate credentials. Credentialing applies to all members of the research team as prescribed below:

**A. Credentialing (see Appendix B “Credentialing Level Requirement Decision Chart”):**

**1. Basic Credentialing:**

- a. This level of credentialing involves the verification of education and experience as described on an applicant’s job or WOC application as well as the completion of a background check; this verification is completed by the Human Resources Office. This level of credentialing is typically required of administrative staff of Albany VAMC who are paid employees of Albany VAMC and whose primary role is administrative, and not investigation/research and do not have a clinical license (or eligibility for one).
- b. Academic Affiliation Credentialing: researchers who function under the supervision of a mentor, who is employed by an organization with which Albany VAMC has an affiliation agreement, have credentials checked and verified through the terms of an

inter-institutional affiliation agreement. The supervisor/mentor from the affiliated institution must agree to oversee the research of the student and affirm the duties outlined in a scope of practice.

## **2. VetPro:**

### **a. VetPro Credentialing**

The VetPro credentialing process applies to any individual involved in research at Albany VAMC; this is especially true of anyone who holds a clinical license, or is eligible for one. The basic VetPro credentialing process uses original document verification in review of applicant histories, including stated education, clinical licensure, job history references.

### **b. VetPro Credentialing and Privileging:**

The VetPro credentialing and privileging process applies to any individual involved in research at Albany VAMC who holds a clinical license, or is eligible for one, as an independent practitioner. The professions identified as independent practitioners are: physicians, nurse practitioners, psychiatrists, psychologists, social workers (see appendix A).

## **3. Exceptions:**

Credentialing and/or validation of qualifications are **NOT** required for the following:

- Research personnel who are based at an affiliate or other outside institution and who will **NOT** access VA patients/data or access VA space for research activities.
- Administrative personnel of Albany VAMC or its nonprofit foundation (ARI) (unless they also hold a clinical license) whose work supports research but does not directly participate in investigation/research activity.
- Outside biostatisticians.
- Outside laboratory technicians.
- Community volunteers who represent the VA on an Institutional Review Board, Institutional Animal Care and Use Committee (IACUC), Subcommittee on Safety and Research Biosafety SRS&B, or the Research & Development (R&D) Committee.
- Participants in data safety monitoring boards who are recruited from non-VA institutions.
- Clinical personnel who periodically perform tests on research patients as part of their routine duties and therefore have already been credentialed through VetPro.
- \* Medicine and Pharmacy residents, as well students from affiliated institutions, who are doing research under the purview of an affiliation agreement with the affiliate and working under the supervision of a mentor from the affiliate institution (the affiliation agreements must stipulate to agreed upon credentialing requirements and affirmation of scope of practice forms).

(see VACO ORD FAQ on credentialing:

<http://www.research.va.gov/programs/pride/credentialing/credentialing-faq.cfm> )

\* Individuals in this group are credentialed through the terms of the institutional affiliation agreement relevant to their area of training and expertise.

## **B. Scope of Practice:**

The Scope of Practice outlines specific research-related duties, including research related clinical duties, as delegated by the Principal Investigator.

The Scope of Practice must be completed and submitted as part of the credentialing documents for all personnel engaged in research. The scope of practice is not required for the Principal Investigator (PI), as their duties, privileges and limits of practice are outlined in their research protocol.

A scope of practice will be developed for each employee, and not each protocol. Research personnel involved in multiple studies under the same PI, will have one scope of practice that encompasses all of the routine duties that they are authorized to perform. Research personnel involved in multiple studies under multiple PI's, will have a scope of practice for each PI. If necessary, miscellaneous duties may be added.

The Scope of Practice is granted and signed by the Principal Investigator(s) and reviewed and approved by the Associate Chief of Staff (ACOS) for Research. The Research Office will oversee and maintain all Scopes of Practice.

Students who participate in Albany VAMC research through an affiliated organization must have their scope of practice reviewed by their affiliate organization mentor/supervisor.

## **5. RESPONSIBILITIES:**

### **a. Associate Chief of Staff for Research and Development or delegate** (e.g. AO/R) responsible for:

1. Notifying HR when an individual has been proposed as a research staff member.
2. Verification of proper credentialing. Human Resources appointment of employees and WOC's will be considered adequate verification of proper credentialing by their office, or by the C&P Office.
3. Maintaining a current list of personnel (VA paid employees and WOC status) that are engaged in research.
4. Notifying Performance Management when an individual, eligible to obtain licensure, registration, or certification by virtue of their education and training has been proposed as a research staff member.
5. Notifying the Quality Management/C&P office when an individual is ceasing participation in Albany VAMC research activities.

### **b. Principal Investigators** involved in research are responsible for ensuring that:

1. All research has been approved by the appropriate research subcommittees and the R&D Committee, before the research commences.
2. All employees under their supervision involved in research have approved scopes of practice statements or clinical privileges that are consistent with the employee's qualifications. The Principal Investigator will provide the Research Office with a copy of the Scope of Practice for each of their personnel engaged in human subject research.
3. All proposed employees on respective protocols have completed required credentialing process.

### **c. Human Resources** is responsible for:

1. Determining the type of credentialing and/or privileging required for research staff
2. Completing background checks on all research staff requesting WOC appointments for research activities, as well as all VA employees.
3. Verification of education and training is completed for those individuals not requiring VetPro, and/or when the R&D program has not opted to use the VetPro process. The individuals stated education and training are verified.

4. Committing individuals to VA appointments.

**d. Employees involved in Human Subject Research are responsible for:**

1. Knowing and adhering to the scope of practice or clinical privileges that have been approved for them.
2. Knowing and adhering to applicable statutes, regulations, and policies related to conducting human subject research.
3. Engaging only in human subjects research activities that have been approved by the IRB (and other appropriate research subcommittees) and the R&D committee.
4. If in an applicable profession, which is eligible for a professional license, or likely to perform patient care of any kind, then there must be timely submission of the VetPro required documentation to Quality Management/C&P. Completing the electronic VetPro data entry or requesting prime source education/training documents are sent directly to Human Resources.

**e. Dependent Credentialing and Privileging (C&P) under the Nursing Service and Independently Licensed Practitioners Privileging under the office of Quality Management (QM) are responsible for:**

1. Assuring timely completion of the VetPro process to facilitate the execution of research activities. (Listing of staff requiring VetPro can be found in VHA Directive 2006-067 and in Appendix A) and confirmation of every completed credential by providing a letter of verification to the R&D office of the finalized credential process and date of completion.
2. Verification of continued licensure & certification (if applicable). Quality Management will verify with the Research Office if individuals are still doing research before the verification process begins.
3. Removal of research staff's credentialed status in VetPro upon termination of research employment, activity or appointment (notification of termination will come from ACOS/R and/or designate regarding research staff status)

**6. PROCEDURE:**

- a. The Principal Investigator (PI) will notify the Research Office as soon as possible of all individuals who will participate in research.
- b. Using the guidelines in this policy, the Research Office will make a recommendation of credentialing method to Human Resources upon request for appointment..

**Steps taken when VetPro is required:**

1. For those individuals who require credentialing through VetPro, the Research Office will assure that the individual completes a VetPro Enrollment Form and the individual will forward this document to the VetPro Coordinator in Quality Management (QM).
2. The Research Office will send an e-mail to the hospital Credentialing coordinator to verify the credentials of independent practitioners are already on file.
3. The VetPro Coordinator will enroll the individual in VetPro, and then provide them with a Release of Information form. The individual will complete the VetPro electronic process and will forward all required paperwork, including the Release of Information form, to the VetPro Coordinator.

4. When the VetPro process has been successfully completed, the Associate Chief of Staff for Research (ACOS/R) will electronically sign the VetPro application. QM will e-mail the ACOS/R and the research administrative assistant when the application is ready for signature.
5. The VetPro Coordinator will send an email to the R&D program office with an attached version of the confirmation letter sent to the applicant, once the VetPro has been completed. This copy will be kept in the R&D program office research staff files.
6. All additional processes that may be required to appoint the individual will then be completed by HR

#### **Steps required when VetPro is Not required**

- The Research Office will provide applicants with the appropriate paperwork related to their proposed appointment type. This will include a Release of Information to have all education/training transcripts sent directly to Human Resources.
- Human Resources will verify experience and education and will note in employee appointment record maintained in Human Resources.
- All additional processes that may be required to appoint the individual will then be completed by HR and communicated to the appropriate overseeing department.
- When appropriate (e.g. students), the institutional affiliate mentor/supervisor will sign a form letter agreeing to provide supervision for duties outlined in the individual's scope of practice. See "attachment a."

#### **7. REFERENCES:**

- a. 2003 VA Stand-down documents,
- b. VHA Handbook 1100.19
- c. VA Handbook 5005, Part II, Chapter 33, Section B
- d. VHA Directive 2003-036 "Credentials and Training of Employees Involved in Human Subjects Research"
- e. VHA Directive 2006-067 Credentialing of Health Care Professionals
- f. VACO Research Document "Requirement for Credentialing of All Research Staff" dated May 10, 2007
- g. VACO ORD Website guidance document, titled "FAQ Credentialing," located at <http://www.research.va.gov/programs/pride/credentialing/credentialing-faq.cfm>

8. **RESCISSIONS:** Memo SL-151-06 dated January 1, 2009

9. **FOLLOW-UP RESPONSIBILITY:** Associate Chief of Staff for Research

10. **AUTOMATIC RESCISSION DATE:** xxxxxxxx , 2012

MARY-ELLEN PICHE, FACHE  
Director

**Appendix A** Staff That Must Be Credentialed in VetPro according to VACO guidelines. Those with \* (asterisk) are independently licensed practitioners and require VetPro with Privileges. Albany VAMC will require all individuals involved in research to be credentialed through the VetPro process unless listed on the excepted list.

Physicians \*  
Psychologist \*  
Social Work \*  
Registered Nurse  
Nurse Practitioner \*  
Physician Assistant  
Practical Nurse  
Dietitian and Nutritionist  
Occupational Therapist  
Physical Therapist  
Diagnostic Radiological Technologist  
Therapeutic Radiological Technologist  
Respiratory Therapist  
Pharmacist  
Optometrist  
Podiatrist  
Dental Assistant  
Dental Hygienist  
Corrective Therapist  
Recreation and/or Creative Arts Therapist  
Medical Technologist  
Medical Technician  
Pharmacy Technician  
Speech Pathologist  
Audiologist  
Orthotist and Prosthetist  
Chiropractor \*

Research administrative personnel, who by the nature of their position have the potential to assume patient care related duties, or oversee the quality of safety of the patient care delivered, e.g. Research Assistants, Project Officers, etc.

## Appendix B

Credentialing Level Requirements Decision Chart					
Appointment Type	Basic/HR Credentialing	Affiliation Agreement based credentialing	Vet Pro	Vet Pro with Privileging	Other VA (not Albany) Credentialing Verificaiton
WOC w/out clinical license			x		
WOC w/clinical license			x		
WOC w/clinical license & ILP				x	
Albany VAMC Paid Employee - Administrative w/out clinical license	x				
Albany VAMC Paid Employee - Administrative w/ clinical license			x		
Albany VAMC Paid Employee Researcher w/out clinical license			x		
Other VAMC Paid Employee Researcher w/out clinical license					x
Other VAMC Paid Employee Researcher w/clinical license			x		
Other VAMC Paid Employee Researcher w/clinical license & ILP				x	
VA Paid Employee Researcher w/ clinical license			x		
VA Paid Employee Researcher w/clinical license & ILP				x	
Student/Trainee from affiliated institution		x			
Student/Trainee from non-affiliated institution w/clinical license			x		
Student/Trainee from non-affiliated institution w/out clinical license			x		
Student/Trainee from non-affiliated institution w/clinical license & ILP				x	
IPA Agreement w/out clinical license			x		
IPA Agreement w/clinical license			x		
IPA Agreement w/clinical license & ILP				x	
<b>Notes:</b>	If an individual is identified with more than one appointment type, then they must be credentialed at the highest credentialing level of those appointments identified				
	"ILP" - Independently licensed practitioner				
	"IPA" - Intergovernmental Personnel Agreement				
	See 'exceptions' for designations not listed here. 'Exceptions' do not require credentialing				
	ILP Assumes that the person will be exercising her/his privileges at Albany VAMC				